K021662
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AUG 1 2 2002

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Magly 6.5mm Cannulated Screws

Submission Information

Name and Address of the Sponsor Of the 510(k) Submission:	Magly Orthopedics, LLC 14241 NE Woodinville-Duvall Road, #415 Woodinville, Washington 98072 425.489.2057 Phone 425.482.0147 Fax
Contact Person:	Dave Stinson
Date Summary Prepared:	May 17, 2002

Device Identification

Proprietary Name:	Magly 6.5mm Cannulated Screws
Common Name:	6.5 Cannulated Screw
Classification:	Screw, Fixation, Bone 21 CFR §888.3040

Predicate Device Identification

The Magly 6.5mm Cannulated Screws are substantially equivalent to that of the predicate DePuy/ACE 6.5mm Titanium Cannulated Cancellous Screws. The Magly 6.5mm Cannulated Screws are similar to the listed predicate device in design, function, materials used, and indications for use.

Device Description

Magly 6.5mm Cannulated Screws are of a single thread profile with a nominal major diameter of 6.5mm and can be used in conjunction with a guide wire for precise placement.

At the distal tip the screws will incorporate 20mm of thread and will embody five cutting flutes that are used for reaming and tapping the thread profile. Located at the thread runout to the shank, we placed two reverse cutting flutes, located 180° to each other, to assist in the removal of the screw.

The screws will be available in 5mm incremental lengths, from 30mm-150mm.

Magly 6.5mm Cannulated Screws will be manufactured from titanium alloy

Intended Use of the Device

Magly 6.5mm Cannulated Screws are generally intended for fracture fixation of large bones and large bone fragments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2002

Mr. Dave Stinson
Partner
Magly Orthopedics, LLC
14241 NE Woodinville-Duvall Road, #415
Woodinville, Washington 98072

Re: K021662
Trade/Device Name: Magly 6.5mm Cannulated Screws
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: May 17, 2002
Received: May 20, 2002

Dear Mr. Stinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K021662

Device Name: Magly 6.5mm Cannulated Screws

Indication(s) for Use:

- Femoral neck fractures
- Metaphyseal fractures of the distal femur and tibia
- Fractures of the tibial plateau
- Fractures of the humerus, olecranon process, scapuls, and os calcis
- Fractures of the sacrum, acetabulum, and pelvic ring
- Fixation of the ileo-sacral joint
- Fusions of the foot and ankle

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021662

(Optional Format 1-2-96)